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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/854,867	05/14/2001	Joan H. M. Knoll	30307-A	9935

7590 05/10/2004

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EXAMINER

MYERS, CARLA J

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 05/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

188

## Office Action Summary

Application No.

09/854,867

Applicant(s)

KNOLL ET AL.

Examiner

Carla Myers

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-45 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

### **Restriction**

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-33, 41, 42 and 43, drawn to nucleic acid probes, and methods of making and using nucleic acid probes, classified in Class 435, subclass 6.

II. Claims 34-38, drawn to DNA sequences having 80% identity with any one of SEQ ID Nos: 429-446, classified in Class 536, subclass 23.1 and 24.33.

III. Claims 39 and 40, drawn to a method of determining the existence of a previously unknown repeat sequence, classified in class 436, subclass 6.

IV. Claims 44 and 45, drawn to a method of determining a chromosome breakpoint, classified in Class 435, subclass 6.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the specific nucleic acid primers of invention II are not required to perform the method of invention I and the nucleic acid primers of invention II can be made in a materially different process, such that the nucleic acids can be chemically synthesized or can be directly isolated from natural sources.

Inventions I and III, I and IV, and III and IV are drawn to patentably distinct methods, requiring different method steps and having different objectives. The methods of invention I require preparing a reaction mixture comprising a labeled single copy nucleic acid probe of at least about 50 nucleotides and detecting hybridization of the

Art Unit: 1634

probe to a target nucleic acid. Invention III requires the use of a "putative single copy nucleic acid probe" and comprises contacting this probe with the genome, determining whether the probe hybridizes at more than three different locations, and determining that the genome contains a previously unknown repeat sequence family if the probe hybridizes at more than three different locations. Invention IV requires providing a pair separate labeled single copy nucleic acid probes that hybridize on opposite sides of a breakpoint, reacting the probes with chromosomal target sequences and detecting hybridization of the pair of probes in order to accomplish the objective of determining a chromosomal breakpoint.

Inventions II and III and Inventions II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the specific nucleic acid primers of invention II are not required to perform the methods of inventions III and IV and the nucleic acid primers of invention II can be made in a materially different process, such that the nucleic acids can be chemically synthesized or can be directly isolated from natural sources. Additionally, the nucleic acids of invention II can be used in a materially different process, such as in general methods for synthesizing or amplifying nucleic acids or antisense methods for inhibiting the expression of nucleic acids.

### **Sequence Election Requirement Applicable Group II**

**3. If Applicant elects invention II, Applicant must further select a single nucleic acid species selected from the group consisting of SEQ ID NO: 429-446 and 480-**

Art Unit: 1634

**613.** It is noted that nucleotide sequences consisting of different nucleotide sequences are structurally and functionally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.14. Applicant is advised that this is a restriction requirement and should **not** be construed as an election of species. Thereby, Applicant is required to elect a single nucleic acid species. With respect to claim 37, it appears that this claim is directed to a DNA sequence produced by PCR using a pair of primers. If this is the case, then with respect to claim 37, Applicant should elect a second nucleic acid that is to be examined together with the first elected nucleic acid. For example, if Applicants elect SEQ ID NO: 429, then with respect to claim 37, Applicants may elect to have SEQ ID NO: 429 and 430 searched.

4. Because these inventions are distinct for the reasons given above and have acquired a different status in the art as demonstrated by their different classification and recognized divergent subject matter and because inventions I-IV require different searches that are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or

Art Unit: 1634


more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (571) 272-0747. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (571)-272-0782.

Papers related to this application may be faxed to Group 1634 via the PTO Fax Center using the fax number (703)-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Carla Myers  
May 3, 2004

  
CARLA J. MYERS  
PRIMARY EXAMINER